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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
09/138,091	08/21/98	AIVAR	C 9491-013-27

024510
PIPER MARBURY RUDNICK & WOLFE LLP
STEVEN B KELBER
1200 NINETEENTH STREET, NW
WASHINGTON DC 20036-2412

HM02/1127

EXAMINER	
SPECTOR, L	
ART UNIT	**PAPER NUMBER**
1647	17

DATE MAILED: 11/27/00

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 9/7/00

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 43-48 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 43-48 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

Part III: Detailed Office Action

The request filed on 9/7/00 for a Continued Prosecution Application (CPA) under 37 37 C.F.R. § 1.53(d) based on parent Application No. 09/138091 is acceptable and a CPA has been established. An action on the CPA follows.

Newly introduced claims 43-48 are under consideration, all previously pending claims having been canceled.

Formal Matters:

The use numerous trademarks such as SEPHAROSE, MONO-SEQ ID NO:, etc. (see page 23) has been noted in this application. Trademarks should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Objections and Rejections under 35 U.S.C. §112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 43-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 43 is indefinite as it is not clear what receptor *other* than c-mpl the claim may encompass. The recitation of "a thrombopoietin receptor" would seem to indicate that the claim is

intended to be broader than that to an agonist of c-mpl, and it is not clear what else is intended to be encompassed.

Claim 1 is further indefinite as it is not clear whether only the antibody is required to have the activity of binding to a thrombopoietin receptor, or whether the fragment or variant must also have that function. In the interest of compact prosecution, the Examiner will apply the prior art as though the fragment of variant were required to retain tpo receptor binding function.

The remaining claims are rejected for depending from an indefinite claim.

Claims 43-48 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement is not commensurate in scope with claims to nucleic acids encoding agonist antibodies to any receptor other than one identified as MPL or c-MPL (claim 43).

As stated in the rejection under 35 U.S.C. §112, second paragraph, above, claim 43 appears to encompass agonist antibodies to receptors other than MPL. The specification discloses only mpl as being the thrombopoietin receptor, and discloses no other TPO receptors. It would require undue experimentation to make or find other TPO receptors and then to make agonist antibodies to said receptors. The specification provides no guidance or direction for such, and while it is believable that such could be found or made, without guidance, direction or any working example of such, and in view of the prior art, which does not recognize any TPO receptor other than MPL, it would require undue experimentation to practice the invention in a manner commensurate in scope with the claims.

Rejections Over Prior Art:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 43-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deng et al. or U.S. Patent Number 5,980,893 (Avraham et al.), either reference in view of Bennett et al., U.S. Patent Number 5,635,388 (all references previously of record).

B. Deng et al., Experimental Hematology 24:1072, 1996. Deng et al. disclose monoclonal antibody BAH-1, which is agonistic for human C-MPL. Deng does not disclose nucleic acid encoding the BAH-1 antibody.

Avraham et al. disclose agonist murine monoclonal antibodies to human C-MPL, and therapeutic compositions comprising such; see abstract, paragraph bridging columns 1-2. The BAH-1 antibody was a preferred embodiment. Chimeric and human antibodies are disclosed at column 4 line 56. Active fragments or other recombinant antibodies are disclosed at column 5, lines 30+. Avraham does not disclose nucleic acid encoding the BAH-1 antibody.

Bennett et al. disclose agonist antibodies to another hematopoietic cytokine receptor, the Flk2/Flt3 receptor. At column 12, beginning at line 27, Bennett et al. disclose that it is routine in the art to obtain DNA encoding the monoclonal antibodies "using conventional procedures", and that it is desirable to do so for the purpose of being able recombinantly produce that antibodies (col. 12 line 38-39), or to modify the antibodies, for instance by humanizing the antibodies (substituting the coding sequence for human heavy and light chain constant domains in place of the homologous murine sequences).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the teachings of Avraham et al. or Deng et al. by obtaining nucleic acids encoding the agonist antibodies, as taught by Bennett et al. One of ordinary skill in the art would have been motivated to do so to allow recombinant production of the antibodies, as taught by Bennett et al., and would particularly have been motivated to apply Bennett's teachings to the MPL receptor agonist antibodies of Avraham et al. or Deng et al. because of the common functions of the receptors involved, and would have expected success at obtaining the nucleic acids, Bennett clearly indicates such to have been routine in the art at that time. Accordingly, the invention as a whole was *prima facie* obvious at the time the invention was made.

Advisory Information:

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 8:00 A.M. to 4:30 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703)308-4623.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 305-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. **Please** advise the Examiner at the telephone number above when an informal fax is being transmitted.

Lorraine Spector, Ph.D.
Primary Examiner

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11/17/00